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March 20, 2003

Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject:

Comments on the HPV Test Plan for 4,5,6,7-tetrachloro-1,3isobenzofurandione (TCPA)

Dear Administrator Whitman:

The following comments on the Solutia, Inc., HPV Challenge test plan for 4,5,6,7-tetrachloro-1,3-isobenzofurandione are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Solutia submitted its test plan on November 8, 2002. 4,5,6,7-tetrechloro-1,3-isobenzofurandion (CAS No. 117-08-8; also known as Tetracholorphthalic Anhydride or TCPA) is produced at a single manufacturing site and the manufacturing operation is a closed continuous process. Due to its potential to cause occupational asthma (Schulueter et al, 1978), Solutia has adopted an airborne exposure guideline of 0.5 mg/m^3 8-hour TWA and 1 mg/m^3 15-minute TWA for this compound. In addition, employees wear eye and skin protection to prevent contact as well as approved respiratory equipment. A limited number of customers use TCPA in dyes/pigments and as a flame retardant in plastics. Finally, there are no known consumer uses of TCPA. Thus, based on these parameters, potential exposure resulting from TCPA-related activities is negligible.

We have reviewed the TCPA test plan in detail, and we applaud the approach taken by Solutia. They have used due diligence on their product and followed the basic tenets of the EPA letter of October 1999 with regard to their data needs assessment. As they state on page 6, "[n]early all HPV Endpoints have been satisfied with data from studies that either were well documented, used OECD guideline methods and conducted in accord with GLPs, or were estimated from acceptable estimation programs. In those cases where data were not available, use of the weight-of-evidence has been applied to support a conclusion that no

additional information is needed. Hence, no further testing for any HPV Endpoints in deemed necessary...."

We are in complete agreement with this assessment, as it is a thoughtful, scientific approach rather than a check-the-box approach, and it reflects adherence to the EPA's stated desire to limit animal use. For example, by estimating that fish toxicity would occur only at levels above the level of solubility for TCPA, no testing of fish is warranted. Similarly, by combining the results of the 90-day Subchronic Rat study and the Rat Developmental Toxicity study, there is no need for a new HPV reproductive toxicity study according to EPA Guidance (USEPA, 1998). Both of the aforementioned study types were OECD Guideline tests (Nos. 408 and 414) and conducted according to GLP. And, finally, in multiple repeat dose studies, there were no observations indicative of an effect on reproductive organs, including testes of rodents.

It is worth reiterating that exposure to TCPA is negligible due to the closed system manufacturing process, its production at only one site, the use of protective gear and the types of uses of the product.

We therefore fully support the HPV Test Plan proposed by Solutia for their product, TCPA. We anticipate that the EPA will review this plan favorably and agree that no new animal tests are required. This will spare the suffering and killing of a significant number of animals. Solutia has demonstrated a thoughtful and scientific approach in their assessment, and such efforts should be encouraged by the EPA in similar assessments.

I look forward to a prompt and favorable response from the EPA on this matter. I may be reached at 202-686-2210, ext. 302, or via email at *csandusky@pcrm.org*.

Sincerely,

Chad B. Sandusky, Ph.D.
Senior Toxicologist

References:

Schlueter, DP, Banaszak, EF, Fink, JN, and Barboriak, j. 1978. Occupational asthma due to tetrachlorophthalic anhydride. *J. Occup. Med.* 20:183-86.

US EPA, 1998. Guidance for meeting the SIDS requirements (The SIDS Guide). Guidance for the HPV Challenge Program (11/31/98).